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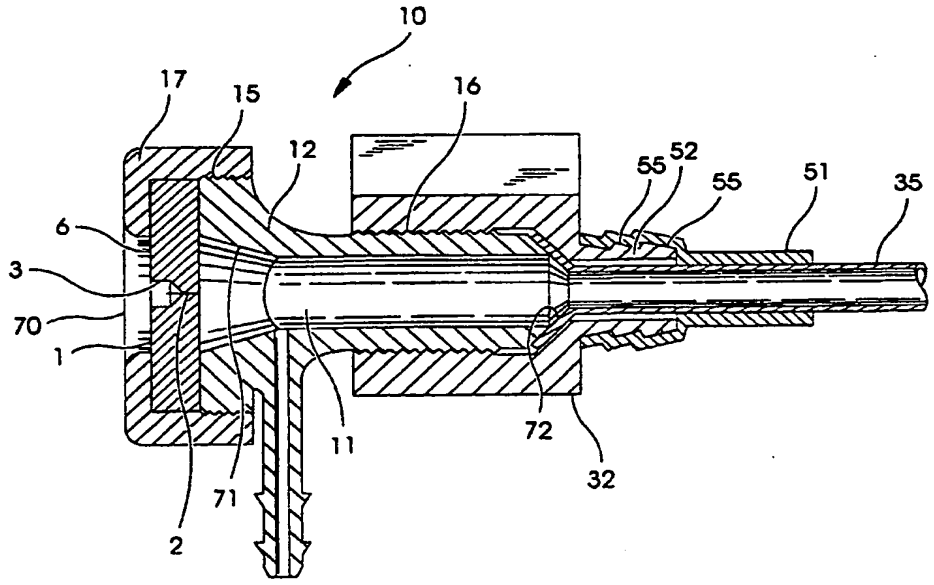

(57) Abstract

This invention is a hemostasis cannula comprising a housing (10) having a passage (11) therethrough sized to receive a catheter and a valve body (1') mounted in the passage. The valve body (1') includes an opening (3') therethrough which forms a seal around a catheter enclosed within the cannula. When the catheter is removed, the valve body (1') closes thus blocking airflow into the patient's blood vessel, and also blocking blood flow out of the patient's blood vessel. The cannula housing (10) also includes a side port (47) for introducing fluids into the patient's blood vessel.

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HEMOSTASIS CANNULA

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part application of copending patent application Serial No. 07/879,430 filed May 6, 1992.

BACKGROUND OF THE INVENTION

This invention relates to a cannula or sheath and particularly to a cannula useful with angiographic catheters.

In certain angiographic studies, the angiographer uses the Desilets-Hoffman procedure to do a multiple study. In this procedure, the angiographer obtains access to a patient's blood vessel by inserting a hollow needle through the skin and into the lumen of the blood vessel. A guide wire is passed through the needle and advanced through the artery or vein into the organ to be studied. The needle is removed leaving the guide wire in the organ. A cannula and dilator are advanced over the wire into the vessel and the dilator is removed along the guide wire. The angiographer then conducts the multiple studies by inserting various types of catheters into the vessel through the cannula or sheath. In order to avoid excessive bleeding and to insure against the possibility of an air embolism, this technique requires occlusion of the passage through the cannula during catheter changes.

One method of obtaining the required occlusion is to

position a valve body formed from a pliable material in the passageway of the cannula. Such valve bodies are shown for instance in U.S. Patent No. 4,000,739 to Stevens, U.S. Patent No. 4,430,081 to Timmermans, U.S. Patent No. 4,610,665 to Matsumoto et al., U.S. Patent No. 5,006,113 to Fischer and International Publication Number WO 91/10459 to Savage et al. In each of these patents, one or more disk-like gaskets are mounted in the cannula passage. The disk-like gaskets or valve bodies include an opening therethrough which is biased to a closed position when no catheter is present in order to prevent an air embolism from occurring by air being drawn into the patient's vein through the cannula. When a catheter is inserted through the valve body into the passage of the cannula, the valve body conforms to the shape of the outer wall of the catheter, thereby preventing blood flow out of the cannula between the catheter and the valve body.

SUMMARY OF THE INVENTION

One embodiment of the present invention might include a hemostasis cannula comprising a housing having a passage sized to receive a catheter therethrough. A valve body formed from a single piece of pliable material is mounted in the passage of the housing. The valve body includes a slit through one face which extends partly through the valve body and an opening through the opposing face extending only partly through the valve body. Both the slit and the opening extend far enough into the valve body that they intersect within the valve body. Also included is a means which contacts a portion of the peripheral edge of the valve body for compressing the valve body in a direction substantially perpendicular to the slit in order to maintain the slit in a fluid-tight seal. The valve body is made of a material which will conform to the shape of the outer wall of a catheter when the catheter penetrates through the slit and opening in the valve body thereby maintaining a fluid-tight seal between the outer wall of the catheter and the valve body.

A further embodiment of the present invention might include a hemostasis cannula comprising a housing having a passage sized to receive a catheter therethrough. A valve body, similar to the valve body described above, formed from a single piece of pliable material is mounted in the passage of the housing. The valve body includes a slit through one planar face which extends partly through the valve body and an opening through the opposing planar face extending only partly through the valve body. Additionally, a raised ring on the opposing planar face surrounds the opening. Both the slit and the opening extend far enough into the valve body that they intersect within the valve body. Also included is a means which contacts a portion of the peripheral edge of the valve body for compressing the valve body in a direction substantially perpendicular to the slit in order to maintain

the slit in a fluid-tight seal.

One object of the present invention is to provide an improved hemostasis cannula.

Another object of the present invention is to provide a method for making an improved hemostasis cannula.

Related objects and advantages of the present invention will be apparent from the following description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view taken axially of a hemostasis cannula of the present invention.

FIG. 2 is an exploded partially cut-away view of the embodiment of FIG. 1.

FIG. 3 is a side elevational view of the cannula having a dilator unit and wire guide therein.

FIG. 4 is a view similar to FIG. 3 showing the cannula in position in the lumen of a blood vessel with a catheter enclosed therein.

FIG. 5 is a front view of the valve body used in the hemostasis cannula of FIGS. 1 and 2.

FIG. 6 is a bottom partially cut-away view of the valve body shown in FIG. 5.

FIG. 7 is a side view of the valve body shown in FIGS. 5 and 6.

FIG. 8 is a view looking axially into the recess portion of the housing of the hemostasis cannula of the present invention showing a front view of the valve body of FIGS. 5-7 before and after it has been compressed and fitted into the recess of the housing.

FIG. 9 is a front view of another valve body according to the present invention.

FIG. 10 is a front view of the valve body shown in FIG. 9 after being compressed.

FIG. 11 is a front view of still another valve body according to the present invention.

FIG. 12 is a front view of the valve body shown in FIG. 11 after being compressed.

FIG. 13 is a front view of a further embodiment of a valve body used in the hemostasis cannula of FIGS. 1 and 2.

FIG. 14 is a bottom partially cut-away view of the valve

body shown in FIG. 13.

FIG. 15 is a side view of the valve body shown in FIGS. 13 and 14.

FIG. 15A is an enlarged view of a portion of the valve body shown in FIGS. 13 - 15.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now more particularly to the drawings, there is illustrated in FIGS. 1 and 2 a hemostasis cannula which includes a housing 10 having a passage 11 therethrough adapted to receive a catheter. Housing 10 is made up of a member 12 having two externally threaded surfaces 15 and 16. A cap 17, which includes recess 18, is threaded down on the member 12 on the threads 15 and is glued in place by a suitable cement or the like. Valve body 1 is received into recess 18 and is sandwiched between cap 17 in member 12. As can be seen in FIGS. 1 and 2, the face 6 including the cylindrical recess or hole 3 of valve body 1 is directed towards the opening 70 of the cap 17.

The cannula housing 10 also includes an internally threaded member 32, the threads of which are suitable for mating engagement with the threads 16 on the member 12. The function of the member 32 is to receive and fix or hold the flexible tubing 35 to the housing 10. In the assembly procedure, adhesive or cement is placed on the flexible tubing 35 and between the members 12 and 32 for affixing the tubing and members together. The flexible tubing 35 has a flared end 36 which is fixed between the tapered surfaces 37 and 40 of the members 12 and 32.

Housing 10 is provided with a port 45 which communicates with passage 11 between valve body 1 and flexible tube 35 for introducing fluids into the patient's blood vessel. In order to ensure that blood does not flow out the flushing port 45, the physician normally maintains a positive pressure of flushing fluid through the flexible tubing 46 (FIGS. 3 and 4), which is attached to the projection 47 by means of the annular ridges 50. The flexible tubing 35 is further secured to housing 10 by means of shrinkable tubing 51 which is secured about collar 52 via the annular ridges 55. As seen in FIG. 3, a hollow plastic dilator 56 having an outer diameter substantially equal to that of catheter 57 (FIG. 4) may be positioned in the passage 11 with the tapered end 60 of the dilator extending past the distal end of tube 35. After the cannula has been inserted into the blood vessel over the guide wire 61 and the dilator 60, the dilator and guide wire may be removed and discarded.

Valve body 1 is oblong in shape and has a height dimension H_2 which is greater than the height dimension H_1 of recess 18. Therefore, valve body 1 must be compressed in the direction of arrows 8 in order to be received within recess 18. Valve body 1 includes a pair of opposing faces 6 which are separated by a peripheral edge 5. A hole or cylindrical recess 3 is made through one of the faces and extends partially through the valve body as shown in FIG. 1. The hole 3 may be formed by molding during the process of forming the disk or punched, cut or drilled in a separate operation. A slit 2 is made through the other face and extends partially through the valve body intersecting hole 3 within the valve body.

Valve body 1 is preferably made from silicon rubber or another elastomer having a durometer hardness anywhere between 20 and 90. Referring to FIGS. 5-8, valve body 1 preferably has an oblong shape such that peripheral edge 5 includes a pair of parallel planar surfaces 4 which are

perpendicular to the plane defined by slit 2. Slit 2 preferably extends completely across one of the faces 6 and extends into the valve body to a depth of between 1/3 and 2/3 the thickness of the valve body. Hole 3 preferably has a diameter between 0.010 and 0.035 inches and, like slit 2, has a depth preferably between 1/3 and 2/3 the thickness of valve body 1. In any event, the combined depth of hole 3 and slit 2 must be sufficient that they intersect within the valve body and create an opening completely through the valve body for receiving a catheter or the like therethrough. Of course, the oblong shape of valve body 1 results in it having a height dimension H_2 which is greater than its width dimension W_2. FIG. 8 shows the valve body 1 both before and after it has been compressed in order to be positioned in recess 18 of housing 10. Before being compressed, valve body 1 has a height dimension H_2 which is greater than height dimension H1 of recess 18 as shown in FIG. 2. So that the compression forces on valve body 1 are directed only perpendicularly to slit 2, valve body 1 has a width dimension W_2 which is less than the width dimension W_1 of recess 18. Planar portions 4 allow valve body 1 to expand in its width dimension without interacting with the recess when it is compressed and received within the recess 18.

FIGS. 9 and 10 show another embodiment of a valve body 101 which can be used with the hemostasis cannula of FIGS. 1 and 2. In this case, valve body 101 is oblong in shape and includes a pair of intersecting slits 102 and 103. The slit configuration of the valve body 101 may be as is more completely described in U.S. Patent No. 4,610,665 to Matsumoto et al., which description is incorporated herein by reference. Alternatively, the intersecting slits 102 and 103 may extend completely across the respective faces of valve 101, as is shown in FIGS. 9 and 10 . The important aspect in this case is that the oblong shape of valve body 101 is compressed along arrows 8 perpendicular to slit 102 so that

the valve body may be received within the recess of a cannula housing as described previously. The compression force 8 improves the performance by insuring that slit 102 remains closed during catheter exchanges.

FIGS. 11 and 12 illustrate still another embodiment of a valve body according to the present invention. In this case, valve body 111 is oblong in shape similar to the shape discussed in reference to valve body 1 shown in FIGS. 5-8. In this case, however, valve body 111 includes a hole 112 completely through the valve body. Hole 112 includes boundary walls 113 and 114 which remain separate when valve body 11 is uncompressed. When sufficient compression is applied to valve body 111, as shown in FIG. 12, boundary walls 113 and 114 are forced together, thus forming a fluid-tight seal through the valve body. Thus, the compression concept of the present invention has application in hemostasis cannulas having two or more valve body gaskets as shown in U.S. Patent No. 4,000,739 to Stevens or U.S. Patent No. 4,430,081 to Timmermans, or to hemostasis cannulas containing a single valve body gasket as shown in U.S. Patent No. 4,610,665 to Matsumoto et al., and U.S. Patent No. 5,006,113 to Fischer.

FIGS. 13-15A show yet another embodiment of a valve body according to the present invention. FIG. 13 is a front view of a valve body 1' which is substantially similar to the valve body 1, with the major difference being the addition of a raised ring or doughnut 7' which surrounds the hole 3'. The valve body 1' may be substituted for the valve body 1 in the hemostasis cannula of FIGS. 1 and 2. Likewise, the face 6' including the cylindrical recess or hole 3' and the raised ring 7' of valve body 1' may be directed towards the opening 70 of the cap 17 (FIGS. 1 and 2).

As with valve body 1, valve body 1' is oblong in shape and has a height dimension H_2' which is greater than the height dimension H_1 of recess 18 of FIG. 1. Therefore,

valve body 1' must additionally be compressed in the direction of arrows 8 in order to be received within recess 18. Valve body 1' includes a pair of opposing planar faces 6' which are separated by a peripheral edge 5'. A hole or cylindrical recess 3' is made through one of the faces and extends partially through the valve body as shown in FIG. 14. The hole 3' may be formed by molding during the process of forming the disk or punched, cut or drilled in a separate operation. A slit 2' is made through the other face and extends partially through the valve body intersecting hole 3' within the valve body. Additionally, a raised ring 7' on the top surface of the valve provides a lead-in to the hole 3' of the valve body 1'. As such, the raised ring 7' makes it easier to place very small diameter devices through the valve. The extra material around the hole 3' additionally makes the valve less likely to tear.

Further, valve body 1' (including raised ring 7') is preferably made from silicon rubber or another elastomer having a durometer hardness anywhere between 20 and 90. Referring now to FIGS. 13-15A, valve body 1' preferably has an oblong shape such that peripheral edge 5' includes a pair of parallel planar surfaces 4' which are perpendicular to the plane defined by slit 2'. Slit 2' preferably extends completely across one of the faces 6' and extends into the valve body to a depth of between 1/3 and 2/3 the thickness of the valve body.

In one particular embodiment of the present invention, the thickness of the valve body 1' may be .062 inches +/- .002 inches and the slit depth may be between .040 and .045 inches. Hole 3' preferably has a diameter of between 0.010 and 0.035 inches and, like slit 2', has a depth preferably between 1/3 and 2/3 the thickness of valve body 1'. In any event, the combined depth of hole 3' and slit 2' must be sufficient that they intersect within the valve body and create an opening completely through the valve body for

receiving a catheter or the like therethrough. Of course, the oblong shape of valve body 1' results in it having a height dimension H_2' which is greater than its width dimension W_2'. For example in the above mentioned particular embodiment of the present valve, height H_2' is between .405 and .410 inches in diameter compared to a width W_2' of between .340 and .360 inches.

The raised ring 7' is centered around the hole 3'. Additionally, as can be seen more clearly in FIG. 15A, the inner wall 9' of the raised ring 7' is sloped from the top of the raised ring 7' down to the face 6'. An angle θ can be measured between a plane parallel to the face 6' and the inner wall 9'. In the above mentioned particular embodiment angle θ is 45°.

Further, in that embodiment, the outer diameter of raised ring 7' is chosen to be between .145 -.155 inches while the inner diameter, measured at the top of the raised ring, may be between .080 -.095 inches in diameter. Additionally, the raised ring may extend between .025 and .030 inches above the face 6'.

As can be further seen in FIG. 15A, in the preferred embodiment, the tapered walls terminate at the surface of the planar face 6' prior to the beginning of the hole 3', thus forming a small planar surface between the hole 3' and the raised ring 7'. Alternately, the sloping inner wall 9' can terminate directly at the edge of the hole 3'.

As with the previous embodiments of the invention, before being compressed, valve body 1' has a height dimension H_2' which is greater than height dimension H_1 of recess 18 shown in FIGS. 1 and 2. So that the compression forces on valve body 1' are directed only perpendicularly to slit 2', valve body 1' has a width dimension W_2' which is less than the width dimension W_1' of recess 18 of FIG. 1. Planar portions 4' allow valve body 1' to expand in its width dimension without interacting with the recess when it is

compressed and received within the recess 18 of FIG. 1.

The compression applied to the valve body could be produced by any of a number of methods. The recess in the housing could be shaped so that it applied the needed pressure to produce a closing force to the opening in the valve body. The closing force produced by the compression on the opening through the valve body improves the performance of most if not all of the valve bodies of the prior art as well as those in accordance with FIGS. 5 - 8 and 13 - 15A. It has been found that valve bodies 1 and 1' both work well with a wide range of device diameters, and because of the compression, the valve body is insensitive to such factors as slit depth and hole diameter.

In operation as shown in FIG. 4, a hollow needle subcutaneously enters the blood vessel. When the lumen 62 of the vessel has been penetrated, guide wire 61 is threaded into the needle and blood vessel, and the needle is removed. A hollow plastic dilator 60 is then passed through passage 11 of the cannula housing and is slid over guide 61. The physician then dilates the hole through the vessel wall by maneuvering the tapered end 60 of the dilator 56, and introduces the entrance tube 35 into vessel lumen 62. It should be noted that the outer diameter of the dilator at its constant diameter portion is close to the outer diameter of the flexible tubing 35 so that tubing 35 is guided through the wall of the vessel by the dilator. The cannula is then taped into position on the body of the patient. With the feed tube 46 fastened to projection 47, and while maintaining a slow flow of heparin saline solution into passage 11 through the tube 46, the physician withdraws dilator 56 and guide 61. At this point, slit 2 or 2' in valve body 1 or 1', respectively, closes. The closure of slit 2 or 2' insures that no air passes through the opening 70 of cap 17 and through valve body 1 or 1' into passage 11. Thus, the present device not only prevents blood loss but also insures

against the possibility of an air embolism.

The catheter 57 is then introduced through the opening in cap 17 and passes through valve body 1 or 1'. Catheter 57 is guided through passage 11 and flexible tubing 35 by the tapered surfaces 71 and 72. The catheter finally passes into lumen 62 of the blood vessel. Hole 3 or 3' (and in the case of valve 1', raised ring 7') forms a seal around the exterior wall of catheter 57 and prevents blood loss through hole 70 in the cap. Passage 11 is constantly flushed by a flow of heparin saline solution introduced through the port 45 and tubing 46 in order to prevent clotting. When catheter 57 has been maneuvered into position, radiopaque fluid is injected through the catheter and X-ray photographs may be taken of the radiopaque configuration of the organ being studied.

When multiple studies are indicated, or if a catheter has not been positioned correctly, the catheter may be easily removed from the cannula housing and replaced with another catheter. Also, a guide wire may be used by passing it through the cannula housing if needed. Because slit 2 or 2' in valve body 1 or 1' closes at the time of removal of the catheter, no bleeding is experienced by the patient and no air is allowed to enter into the patient's blood vessel in the event that the pressure external of the cannula is greater than the pressure within the blood vessel.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. For example, the recess in the cannula housing can have various shapes so long as the valve body is of a corresponding cooperating shape to provide compression force in an appropriate direction tending to close the opening in the valve body. It is to be understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

WHAT IS CLAIMED IS:

1. A hemostasis cannula comprising:

a housing having a passage sized to receive a catheter having an outer wall and a blunt end;

a valve body formed from a single piece of pliable material and mounted in said passage of said housing, said valve body having a first planar face, a second planar face and a peripheral edge separating said faces, said first face including a slit extending entirely across said first planar face and defining a slit plane extending only partly through said valve body, said second planar face including a cylindrical recess partly through said valve body, said slit intersecting said cylindrical recess within said valve body;

means, contacting a portion of said peripheral edge, for compressing said valve body only in a direction substantially perpendicular to said slit plane to maintain a fluid tight seal through said valve body;

said valve body conforming to said outer wall of said catheter without cutting said pliable material when said blunt end of said catheter penetrates into said passage through said slit and said cylindrical recess of said valve body thereby maintaining a fluid tight seal between said outer wall of said catheter and said valve body;

said slit and said cylindrical recess being formed in said valve body while unstressed before being mounted in said passage of said housing;

said second planar face including a raised ring of pliable material surrounding said cylindrical recess; and

said peripheral edge including a first planar edge and a second planar edge, said first and second planar edges being substantially perpendicular to said slit plane.

2. The hemostasis cannula of claim 1, wherein:

said valve body has a height dimension perpendicular to said slit plane;

said means for compressing including a housing recess formed in said passage of said housing and having a height dimension across said housing recess less than said height dimension of said valve body;

said housing recess having a height dimension across said housing recess less than said height dimension of said valve body; and

whereby said valve body is compressed along a line perpendicular to said slit plane when said valve body is received within said housing recess.

3. The hemostasis cannula of claim 2 wherein said valve body has a width dimension perpendicular to said height dimension, said width dimension extending between said first and second planar edges; and

said housing recess has a width dimension greater than said width dimension of said valve body.

4. The hemostasis cannula of claim 3 wherein said cylindrical recess has a circular cross section.

5. The hemostasis cannula of claim 4 wherein said slit extends completely across said first face.

6. A hemostasis cannula comprising:

a housing having a passage sized to receive a catheter having an outer wall and a blunt end;

a valve body formed from a single piece of pliable material and mounted in said passage of said housing, said valve body having a first face, a second face and a

peripheral edge separating said faces, said first face including a single planar slit defining a slit plane extending only partly through said valve body, said second face including an opening extending only partly through said valve body, said slit intersecting said opening within said valve body, said second face additionally including a raised portion of pliable material surrounding said opening;

means, contacting a portion of said peripheral edge, for compressing said valve body only in a direction substantially perpendicular to said slit plane to maintain a fluid tight seal through said valve body;

said valve body being capable of conforming to said outer wall of said catheter without cutting said pliable material when said blunt end of said catheter penetrates into said passage through said slit and said opening of said valve body thereby maintaining a fluid tight seal between said outer wall of said catheter and said valve body; and

said slit and said opening being formed in said valve body while unstressed before being mounted in said passage of said housing.

7. The hemostasis cannula of claim 6 wherein said opening is a cylindrical recess.

8. The hemostasis cannula of claim 7 wherein said valve body has a height dimension perpendicular to said slit plane;

said means for compressing includes a housing recess formed in said passage of said housing and having a height dimension across said housing recess less than said height dimension of said valve body; and

whereby said valve body is compressed along a line perpendicular to said slit plane when said valve body is received within said housing recess.

9. The hemostasis cannula of claim 8 wherein said cylindrical recess has a circular cross section.

10. The hemostasis cannula of claim 9 wherein said valve body has a width dimension perpendicular to said height dimension; and

said recess of said housing has a width dimension greater than said width dimension of said valve body.

11. The hemostasis cannula of claim 10 wherein said peripheral edge of said valve body includes a pair of substantially planar surfaces perpendicular to said slit plane, said width dimension of said valve body being the distance between said planar surfaces.

12. The hemostasis cannula of claim 11 wherein said planar slit extends completely across said first face.

13. The hemostasis cannula of claim 6 wherein said opening includes a second slit oriented at an angle with respect to said planar slit.

14. The hemostasis cannula of claim 13 wherein said valve body has a height dimension perpendicular to said slit plane;

said means for compressing includes a housing recess formed in said passage of said housing and having a height dimension across said housing recess less than said height dimension of said valve body; and

whereby said valve body is compressed along a line perpendicular to said slit plane when said valve body is received within said housing recess.

15. The hemostasis cannula of claim 14 wherein said angle is about 90 degrees.

16. The hemostasis cannula of claim 14 wherein said first slit extends completely across said first face.

17. The hemostasis cannula of claim 14 wherein said second slit extends completely across said second face.

18. A method for making a hemostasis cannula comprising the steps of:

providing a housing having proximal and distal ends, said housing including a housing recess and a passage sized to receive a catheter having an outer wall and a blunt end, said housing recess having a first height dimension and a first width dimension perpendicular to said first height dimension;

providing a valve body formed from a single piece of pliable material, said valve body having a first planar face, a second planar face and a peripheral edge separating said faces, said first planar face including a slit defining a slit plane extending only partly through said valve body, said second planar face including a cylindrical recess partly through said valve body, said slit intersecting said cylindrical recess within said valve body, said second planar face including a raised ring of pliable material surrounding said cylindrical recess; and wherein said valve body additionally includes a second height dimension and a second width dimension perpendicular to said second height dimension and to said slit plane, said second height dimension of said valve body being greater than said first height dimension of said housing recess and said second width dimension of said

valve body being less than said first width dimension of said housing recess;

receiving said valve body within said housing recess with said second face directed towards said proximal end of said cannula housing such that said valve body is compressed only in a direction substantially perpendicular to said slit plane when said valve body is received within said housing recess.

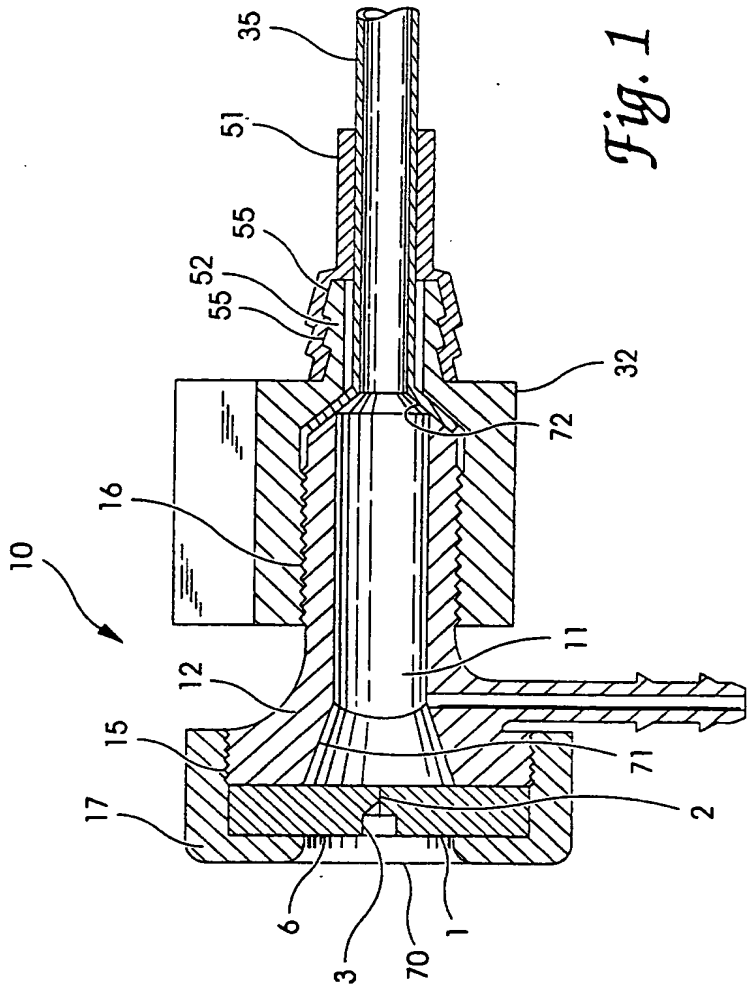

Fig. 1

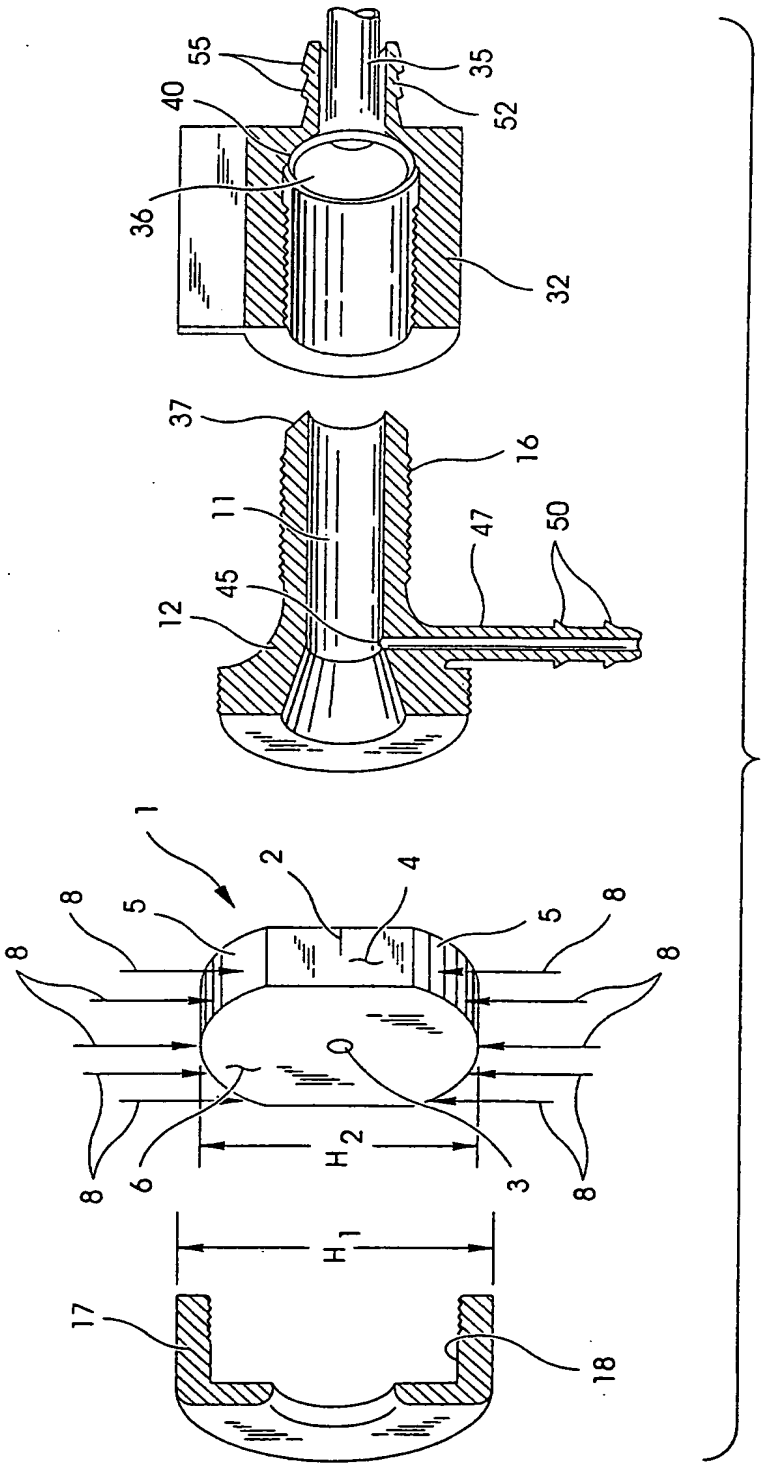

Fig. 2

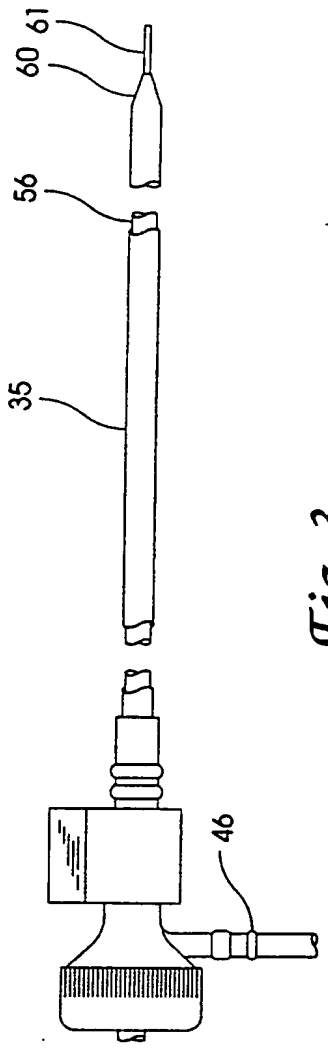

Fig. 3

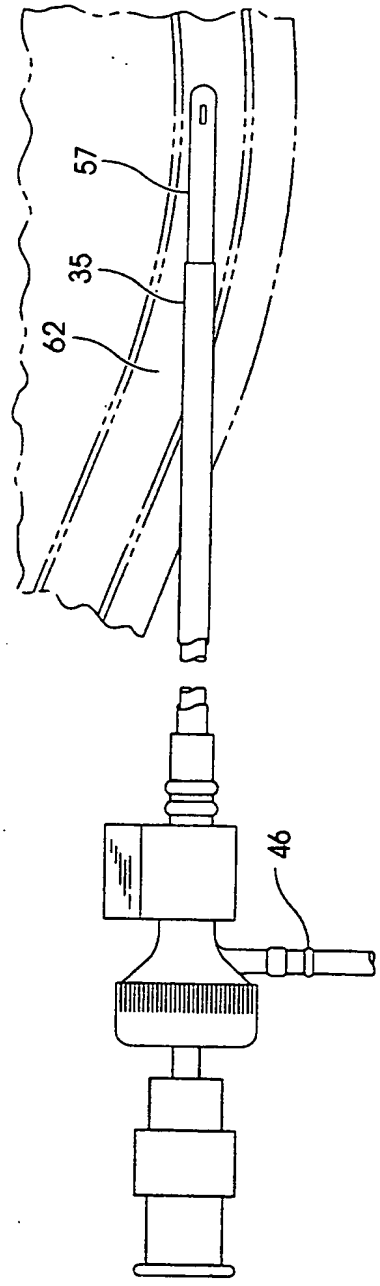

Fig. 4

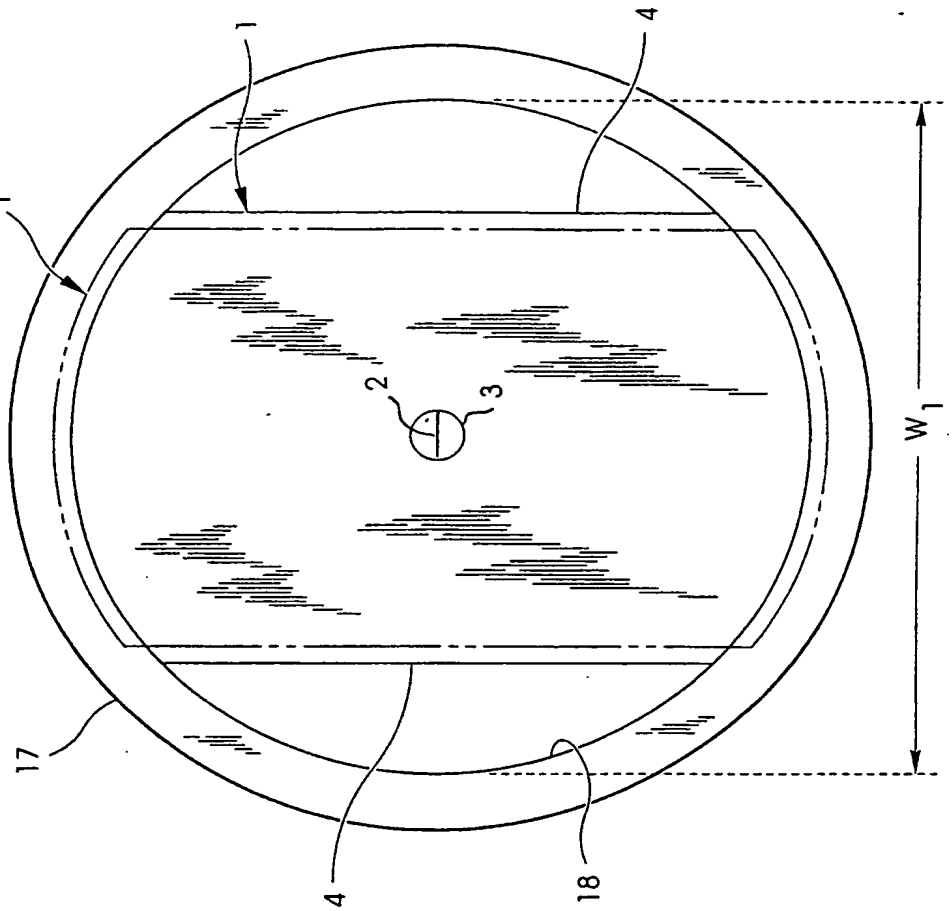

Fig. 8

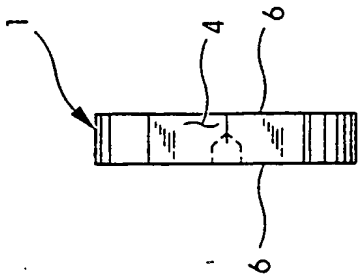

Fig. 7

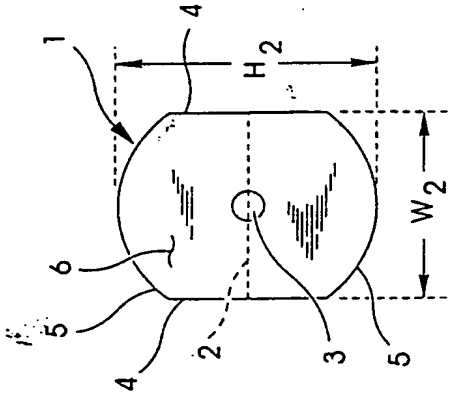

Fig. 5

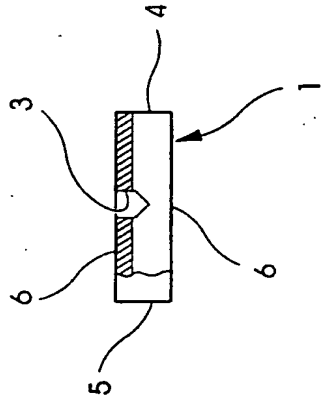

Fig. 6

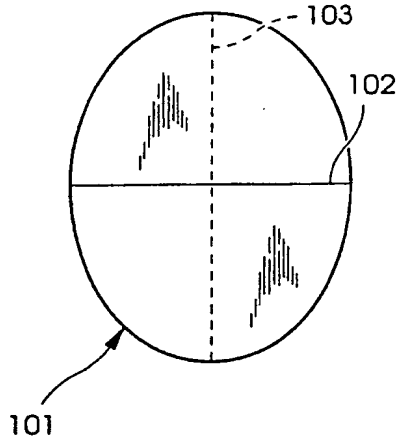

Fig. 9

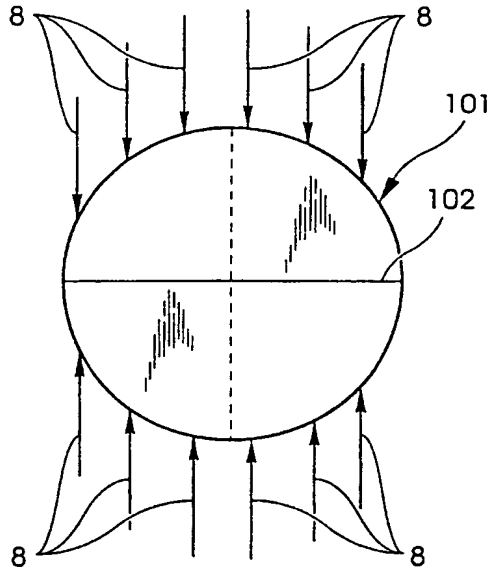

Fig. 10

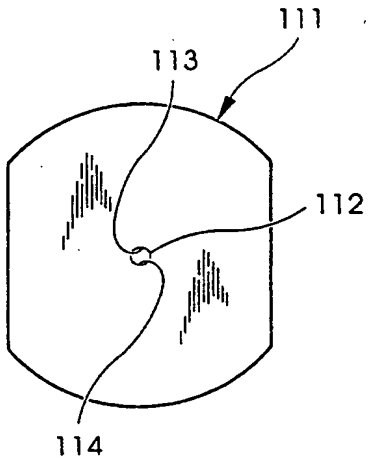

Fig. 11

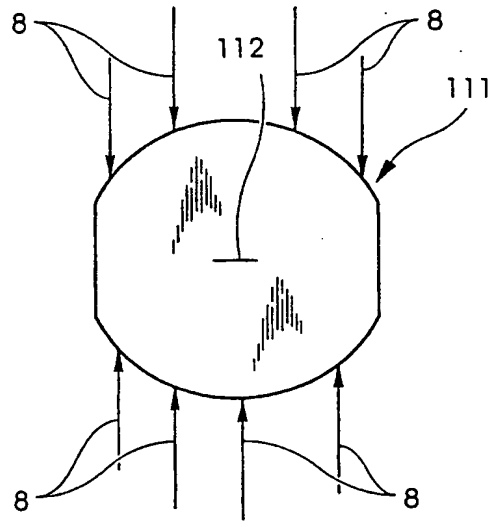

Fig. 12

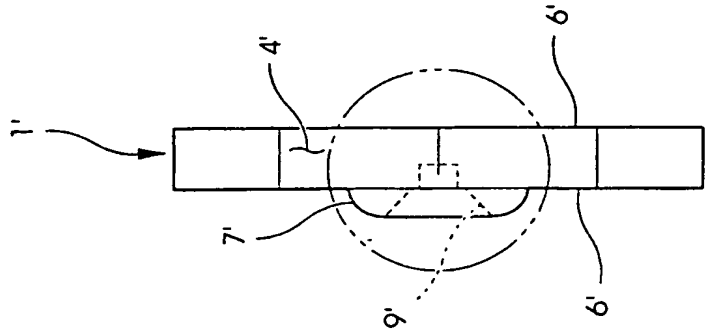

Fig. 15

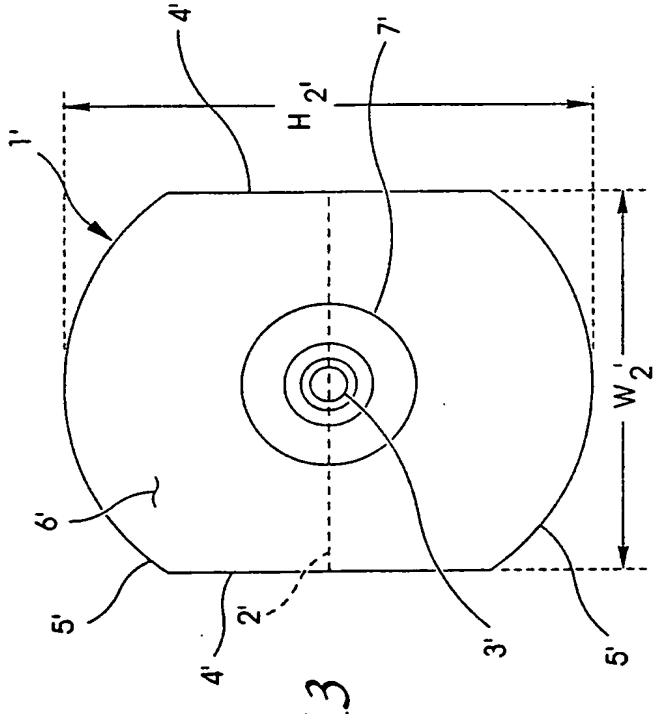

Fig. 13

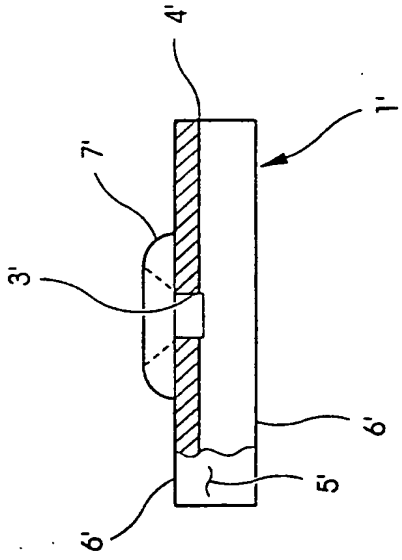

Fig. 14

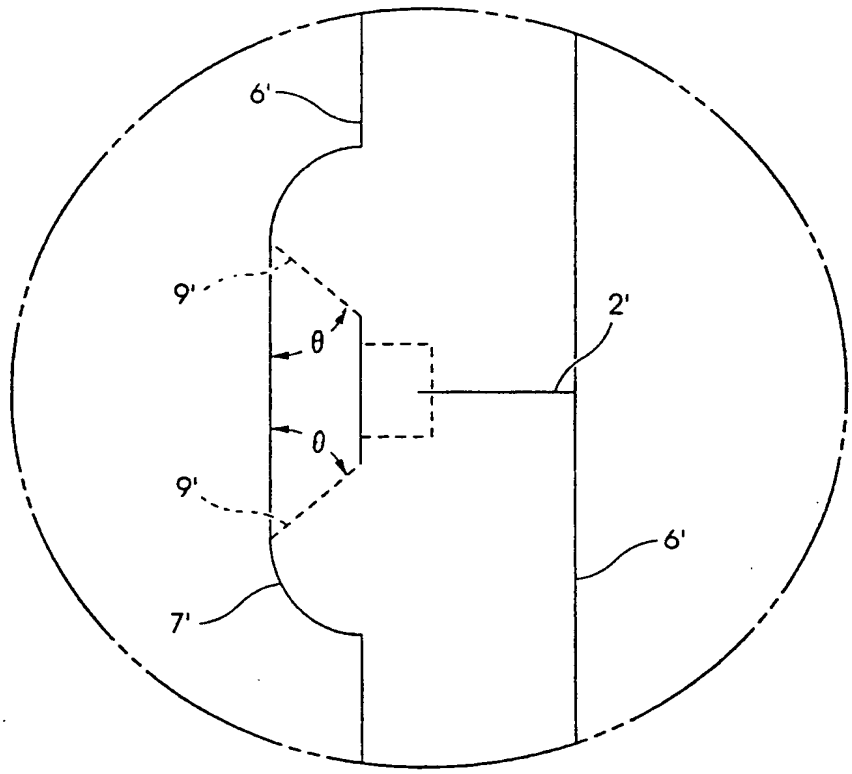

Fig. 15A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/01979

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00, 5/14, 5/178
US CL :604/167, 256
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 251/149.1-149.3; 604/19, 30, 31, 104, 122, 158, 164, 167, 169, 174, 175, 180, 244, 255, 256, 260, 267, 272, 903

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,610,665, (MATSUMMOTO ET AL.), 09 September 1986. See figures, and column 8 lines 15-21.	1-18
Y	US, A, 3,853,127, (SPADEMAN), 10 December 1974. See Figs, 7A-7D.	1-18
Y	US, A, 4,809,679, (SHIMONAKA ET AL.), 07 March 1999. See Fig. 5C.	1-18
Y	US, A, 5,006,133, (FISCHER), 09 April 1991. See column 3, lines 46-55.	5, 12, 16, 17
Y	US, A, 5,114,408, (FLEISCHHAKER ET AL.), 19 May 1992. See figures.	1-5, 18
P	US, A, 5,211,633, (STOUDER, JR.), 18 May 1993. See figures, and column 3 lines 37-48	1-5

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
10 APRIL 1995	24 APR 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer KARIN M. REICHLE Telephone No. (703) 308-2617

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